

DETAILED ACTION

1. This office action is in response to the amendment of 7/5/11 and the interview of 9/28/11. As directed by the amendment, claims 1, 3-6, 8-12, 14, 16, 18-20, 22, 25, 28-31, and 33-35 have been amended, claim 27 has been cancelled, and claim 36 has been added. Per the interview and the examiner's amendments below, the application is in condition for allowance of claims 1-26 and 28-36.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Jeffrey Gluck 44457 on 9/28/11.

The application has been amended as follows:

Claim 11. (Currently Amended) Device according claim 1, wherein the control means comprises dilution means for mixing the aerosol with a fluid, ~~such as an unsaturated gas~~, for thereby decreasing the dew point of the aerosol.

Claim 13. (Currently Amended) Device according to claim 12, wherein the supply means comprises a container, ~~such as a canister~~, for storing a gaseous substance.

Claim 17. (Currently Amended) Device according to claim 14 or 16, wherein the supply means comprises a container for storing a propellant, ~~such as CO₂~~, and a liquid and/or solid substance.

Claim 25 (Currently Amended) Method for creating an aerosol in an inhalation device; comprising the steps of:

- a) creating an aerosol by means of aerosol means in the inhalation device,
- b) adjusting the state and condition of the aerosol using control means, in order to manipulate the characteristics of the aerosol, including at least its uniformity and/or its mean particle size,
- c) releasing the aerosol from an opening of the device, and
- d) adding a substance to the aerosol, prior to or upon release of the aerosol from the device in order to release the substance from the opening using the aerosol as a carrier, wherein step d) is executed after execution of step b).

Claim 34. (Currently Amended) Method according to ~~claim 26~~ claim 29,

wherein the method comprises the step of:

- i) using the results of steps e) and f) to calculate a preferred timing for the adding of the substance to the aerosol.

REASONS FOR ALLOWANCE

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3. The following is an examiner's statement of reasons for allowance: when read in light of the limitations of the claimed inhalation device (and method of creating aerosol in an inhalation device), the prior art by itself or in combination does not disclose or suggest a device/method which includes an aerosol means and control means, which applicant has invoked 112 6th paragraph to include at least a catalytic burner/fuel cell which uses waste water vapor as the aerosol means and a condensation chamber/dilution chamber, which function to create an aerosol and to then adjust the state and condition of the aerosol, its uniformity and/or mean particle size, and to then adding a substance via a supply means prior to or upon release of aerosol from the device via an opening, wherein the supply means and supplying a substance step occurs after an adjustment of the state and condition of the aerosol by the control means.

The closest prior art references are: Esser (WO 03/094640), Clearman et al. (4,756,318), Hale et al. (2003/0209240), and Cook et al. (5,944,025).

The prior art of record does not disclose or suggest in combination the limitations of the inhalation (and method of creating aerosol in an inhalation device) which includes an aerosol means and control means, which applicant has invoked 112 6th paragraph to include at least a catalytic burner/fuel cell which uses waste water vapor as the aerosol means and a condensation chamber/dilution chamber, which function to create an aerosol and to then adjust the state and condition of the aerosol, its uniformity and/or mean particle size, and to then adding a substance via a supply means prior to or upon release of aerosol from the device via an opening, wherein the supply means and

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supplying a substance step occurs after an adjustment of the state and condition of the aerosol by the control means. The Clearman, Hale, and Cook references related to simulated smoking devices which function to use a catalytic reaction of a burning fuel element which heats another aerosol element to release aerosol which is entrained with a substance (i.e. flavored tobacco etc.) and delivered to the user. These references do not teach the particular fuel cell which uses waste water vapor as an aerosol means and are completely silent as to any control means, condensation chamber/dilution chamber, to adjust the state and condition of the aerosol, its uniformity and/or mean particle size, let alone a control/adjustment before the aerosol is entrained with a substance as claimed in the device and method claims 1 and 25 respectively. The Esser reference is a similar inhaler device which uses a fuel cell whose waste water vapor is used as an aerosol carrier for a substance. However, Esser is silent as to teaching or suggesting a control means, condensation chamber/dilution chamber, to adjust the state and condition of the aerosol, its uniformity and/or mean particle size prior to the adding of a substance. Esser teaches a mixing chamber in which the aerosol carrier, water vapor, the substance, and an optional additional ambient air is mixed together at the same time, and does not provide any teaching of adjustment of the aerosol before addition of the substance as claimed in the device and method claims 1 and 25 respectively.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN W. STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-Thr 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN W STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771